

Remarks

Claims 46-50, 55 and 57-60 are pending in the subject application and are currently before the Examiner. Favorable consideration of the pending claims is respectfully requested.

Applicants gratefully acknowledge the Examiner's withdrawal of the objections to the specification and the rejections under 35 U.S.C. § 112, first and second paragraphs, and 35 U.S.C. § 102(e).

Claims 46-50, 55 and 57-60 have been rejected under 35 U.S.C. 102(e) as being anticipated by Tang *et al.* (reference submitted by Applicant; WO 02/074961 A1). The Office Action argues that Tang *et al.* teach a polypeptide that is 100% identical to instant SEQ ID NO: 2. It is also argued that Tang *et al.* teach methods for treating medical conditions which comprise the step of administering to a mammalian subject a therapeutically effective amount of a composition comprising a polypeptide of the present invention and a pharmaceutically acceptable carrier (page 5, lines 18-21; page 34, lines 19-21 and page 76, lines 11-30). The Office Action further asserts that Tang *et al.* teach that a composition of the present invention is useful for treatment of lung or liver fibrosis (page 55, lines 24-26) and that Tang *et al.* teach that if the protein is made in yeast or bacteria, it may be necessary to modify the protein produced therein, for example by phosphorylation or glycosylation of the appropriate sites, in order to obtain the functional protein. Such covalent attachments may be accomplished using known chemical or enzymatic methods (page 31, lines 27-31). Tang *et al.* is also asserted to teach fusion proteins (page 21, lines 17-20; page 38, lines 1-10; page 39, line 20-page 41, line 5) and that the fusion protein can be an immunoglobulin fusion protein in which the polypeptide sequences according to the invention comprise one or more domains fused to sequences derived from a member of the immunoglobulin protein family (page 40, lines 7-11). Finally, the Office Action argues that Tang *et al.* teach that the proteins may be fused to cytokines alpha or beta interferon (page 39, lines 30-31) and that it is contemplated that interferons may be administered in combination with the polypeptide of the invention (page 77, lines 13-21). Tang *et al.* is also alleged as teaching that the polypeptide and exogenous factors may be administered simultaneously, sequentially or separately (pages 77-79 and 85). Applicants respectfully submit that the cited prior art reference fails to anticipate the claimed invention and that the Patent Office as

simply selected various excerpts from the cited prior art reference in establishing the novelty rejection of record.

The Federal Circuit has rejected efforts to establish that a claimed invention lacked novelty by cobbling together various elements within a prior art reference. In *Net Moneyin, Inc. v. Verisign, Inc.*, 545 F.3d 1359, (Fed. Cir. 2008):

VeriSign responds that the district court did not improperly rearrange the links in the iKP reference, but rather “merely relied on various express teachings from a single document that together completely disclose the five claimed links.” Appellees’ Br. at 61. Under VeriSign’s theory, this was sufficient to establish anticipation, because all that is required is “that the four corners of a single, prior art document describe every element of the claimed invention.” *Id.* at 61-62 (quoting *Xerox Corp. v. 3Com Corp.*, 458 F.3d 1310, 1322 (Fed. Cir. 2006)). We disagree with VeriSign, and take this opportunity to clarify what a reference must show in order to anticipate a claimed invention.

Section 102(a) provides that an issued patent is invalid if “the invention [therein] was . . . described in a printed publication . . . before the invention thereof by the applicant.” Section 102 embodies the concept of novelty—if a device or process has been previously invented (and disclosed to the public), then it is not new, and therefore the claimed invention is “anticipated” by the prior invention. As we have stated numerous times (language on which VeriSign relies), in order to demonstrate anticipation, the proponent must show “that the four corners of a single, prior art document describe every element of the claimed invention.” *Xerox*, 458 F.3d at 1322 (quoting *Advanced Display Sys., Inc. v. Kent State Univ.*, 212 F.3d 1272, 1282 (Fed. Cir. 2000)). This statement embodies the requirement in section 102 that the anticipating invention be “described in a printed publication,” and is, of course, unimpeachable. But it does not tell the whole story. Because the hallmark of anticipation is prior invention, the prior art reference—in order to anticipate under 35 U.S.C. § 102—must not only disclose all elements of the claim within the four corners of the document, but must also disclose those elements “arranged as in the claim.” *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 1548 (Fed. Cir. 1983).

The meaning of the expression “arranged as in the claim” is readily understood in relation to claims drawn to things such as ingredients mixed in some claimed order. In such instances, a reference that discloses all of the claimed ingredients, but not in the order claimed, would not anticipate, because the reference would be missing any disclosure of the limitations of the claimed invention “arranged as in the claim.” But the “arranged as in the claim” requirement is not limited to such a narrow set of “order of limitations” claims. Rather, our precedent informs that the “arranged as in the claim” requirement applies to all claims and refers to the need for an anticipatory reference to show all of the limitations of the claims arranged or combined in the same way as recited in the claims, not merely in a particular order.

The test is thus more accurately understood to mean “arranged or combined in the same way as in the claim.”

In the case of the instantly claimed invention, Applicants respectfully submit that Tang *et al.* fail to disclose all the elements of the claim and the reference also fails to teach the claimed elements “arranged or combined in the same way as in the claim.” Particularly, Applicants note that the cited prior art reference states, at pages 7, lines 3-7:

The polypeptides of the present invention and the polynucleotides encoding them are also useful for the same functions known to one of skill in the art as the polypeptides and polynucleotides to which they have homology (set forth in Table 2); for which they have a signature region (as set forth in Table 3); or for which they have homology to a gene family (as set forth in Table 4).

In this regard, Applicants note that the polypeptide corresponding to SEQ ID NO: 913 is not associated with a polypeptide associated as useful for the treatment of liver or lung fibrosis. Thus, it cannot be said that the reference teaches or suggests its use in such a treatment protocol. Particularly, Table 2 indicates that the polypeptide has homology to the human SEC protein of the *sec* oncogene or a human hematopoietic/immune antigen (see Table 2, page 177). The polypeptide is not listed in Tables 3 or 4; thus, the polypeptide was not recognized as having homology to a signature region or homology to a gene family at the time the cited reference was filed. Thus, at best, one skilled in the art, in view of the teachings of the reference, would have used the polypeptide associated with SEQ ID NO: 913 in methods of detecting cancers or, possibly, for detecting elements of the human hematopoietic/immune systems. Indeed, the description of the reference would indicate that a polypeptide with similarities to an oncogene or a human hematopoietic/immune antigen would be used in assays such as those discussed at sections 3.10.3-3.10.5 (see pages 47-53) or section 3.10.11 (pages 64-66). The teachings of the reference would not have indicated that the claimed polypeptide should have been used for the treatment of liver or lung fibrosis.

Applicants have also reviewed the database entry associated with the Q9BTA0 accession number and note that the gene was isolated from melanoma, see attached printout (at page 1, six lines from the bottom). Thus, it is respectfully submitted that those skilled in the art, at the time the invention was made, would not have recognized that the polypeptide of SEQ ID NO: 913 should have been used for the treatment of liver or lung fibrosis. Accordingly, reconsideration and

withdrawal of the rejection of record is respectfully requested as Tang *et al.* fail to disclose all the elements of the claim and the reference also fails to teach the claimed elements "arranged or combined in the same way as in the claim."

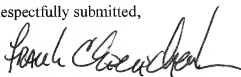
It should be understood that the amendments presented herein have been made solely to expedite prosecution of the subject application to completion and should not be construed as an indication of Applicants' agreement with or acquiescence in the Examiner's position. Applicants expressly reserve the right to pursue the invention(s) disclosed in the subject application, including any subject matter canceled or not pursued during prosecution of the subject application, in a related application.

In view of the foregoing remarks and amendments to the claims, Applicants believe that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

Applicants invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephonic interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,



Frank C. Eisenschenk, Ph.D.

Patent Attorney

Registration No. 45,332

Phone No.: 352-375-8100

Fax No.: 352-372-5800

Address: P.O. Box 142950

Gainesville, FL 32614-2950

FCE/jb/sl

Attachment: Accession Number Q9BTA0 database entry